

Notice of Allowability	Application No.	Applicant(s)	
	10/619,532	MUKERJI ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 3 October 2006 and the interview conducted 16 November 2006.
2. ☒ The allowed claim(s) is/are 1,2,6-9,12-16,21 and 23.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Cancel claims 3, 4, 10, 11, 17-20, 22, 24, and 25.

Amend claims 1, 2, 6, 15, 21, and 23 thus:

Claim 1 (Amended): An isolated nucleic acid having a sequence of nucleotides comprising or complementary to a nucleic acid sequence encoding a polypeptide having polyketide synthase activity with a substrate selected from the group consisting of acetyl-CoA, malonyl-CoA, and methylmalonyl-CoA, wherein the amino acid sequence of said polypeptide has at least 95% amino acid sequence identity to the an amino acid sequence set forth in comprising SEQ ID NO:10.

Claim 2 (Amended): An isolated nucleic acid sequence having a sequence of nucleotides comprising or complementary to a nucleic acid sequence having at least 90% nucleotide sequence identity to the a nucleic acid sequence set forth in comprising SEQ ID NO:8, wherein said isolated nucleic acid sequence encodes a polypeptide having polyketide synthase activity with a substrate selected from the group consisting of acetyl-CoA, malonyl-CoA, and methylmalonyl-CoA.

Claim 6 (Amended): The isolated nucleic acid sequence of claim 1, wherein said polyketide synthase permits modulates the production of at least one polyunsaturated fatty acid when expressed in a host cell.

Claim 12 (Amended): A method of producing a polyketide synthase ~~enzyme~~ comprising ~~the steps of:~~

a) isolating a nucleic acid sequence comprising SEQ ID NO:8;

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- b) constructing a vector comprising said isolated nucleic acid sequence operably linked to a regulatory sequence; and
- c) introducing said vector into an isolated a host cell ~~for a~~ under time and under conditions sufficient for expression of said polyketide synthase ~~enzyme~~, whereby said polyketide synthase ~~enzyme~~ is produced.

Claim 15. (Amended): An isolated A host cell comprising the ~~said~~ vector of claim 14.

Claim 21 (Amended): A method for producing a polyunsaturated fatty acid comprising ~~the steps of:~~

- a) isolating a nucleic acid sequence comprising SEQ ID NO:8 ~~or SEQ ID NO:9~~;
- b) constructing a vector comprising said isolated nucleic acid sequence operably linked to a regulatory sequence;
- c) introducing said vector into an isolated a host cell for a time and under conditions sufficient for expression of the polyketide synthase ~~enzymes~~ encoded by said isolated nucleic sequence;
- d) exposing said polyketide synthase ~~enzymes~~ to a substrate selected from the group consisting of acetyl-CoA, malonyl-CoA, and methylmalonyl-CoA, to produce an acyl-chain intermediate a product; and
- e) exposing said acyl-chain intermediate product to at least one enzyme selected from the group consisting of a ketosynthase, a ketoreductase, a dehydratase, an isomerase, an enoyl reductase, a desaturase, and an elongase, whereby said in order to produce said polyunsaturated fatty acid is produced.

Claim 23 (Amended): The method of claim 21, wherein said polyunsaturated fatty acid is selected from the group consisting of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

Authorization for this examiner's amendment was given in a telephone interview with Ms. Cheryl L. Becker on 16 November 2006.

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The following is an examiner's statement of reasons for allowance:

The examiner's amendment rejoins method claims 21 and 23 and clarifies claims 1, 2, 6, 12, and 21 (i) by requiring a specific amino acid sequence and a specific nucleic acid sequence for determining a stated degree of percentage identity in claims 1 and 2, (ii) by indicating disclosed substrates for the biosynthetic activity of a disclosed polyketide synthase, (iii) by replacing the ambiguous term "modulates" in claim 6 with the more appropriate term, "permits", and (iv) by removing unnecessary recitations of "enzyme" and "enzymes" in claims 12 and 21. The examiner's amendment places the rejoined method claims 21 and 23 in condition for rejoinder by removing non-examined subject matter from claim 21 and incorporating in claim 21 the disclosures at pages 30-32 of the specification to clarify the nature of substrates, intermediate products, and final products. The examiner's amendment also ensures that a host cell of claim 15 is not present within a non-elected transgenic organism, and that methods of claims 21 and 23 do not utilize a host cell in a non-elected transgenic organism, thus permitting the allowance of claims 1, 2, 6-9, 12-16, 21, and 23 herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary

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Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
16 November 2006



NASHAAT T. NASHED PHD.
PRIMARY EXAMINER